TrueRelief
% Kristen Allen
Founder and Principal Consultant
AllenBridge Consulting
2221 Oleander Drive
Wilmington, North Carolina 28403

March 23, 2021

Re: K202186
Trade/Device Name: TrueRelief Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: March 16, 2021
Received: March 17, 2021

Dear Kristen Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
TrueRelief Device

Indications for Use *(Describe)*
The TrueRelief Device is intended for use under the supervision of a Healthcare Professional.
TrueRelief is intended for temporary symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TrueRelief

510(k) Summary

TrueRelief Device

Submitter:	TrueRelief 100 Wilshire Boulevard, Suite 700 Santa Monica, CA 90401 310.918.9064 (P)
Contact Person:	Kristen Allen Principal Consultant, Regulatory, Quality and Compliance 910-612-4153 (P) kallen@truerelief.com

Date Prepared:	March 23, 2021
Trade Name:	TrueRelief Device
Common Name:	Transcutaneous Electrical Nerve Stimulator (TENS) for pain relief
Device Product Code and Classification:	Regulation Number: 21 CFR 882.5890 **GZJ**, Class II, Transcutaneous Electrical Nerve Stimulator (TENS) for pain relief
Primary Predicate:	TrueRelief Device (originally NewLife Sciences TMR device), K070474
Additional Predicates:	DJO Chattanooga Revolution Wireless, K153696

Device Description:
The TrueRelief device is an AC power operated device that consists of three main components and associated power cables: the pulse generator, a primary probe and a secondary probe. The signal generator applies electromagnetic energy transcutaneously through the primary and secondary probes into painful tissue, similar to Transcutaneous Electrical Nerve Stimulation (TENS) device. The TrueRelief device uses a proprietary waveform with small voltage fluctuations to achieve pain relief.

Indications and Intended use:
The TrueRelief Device is intended for use under the supervision of a Healthcare Professional.

TrueRelief is intended for temporary symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

TrueRelief

Comparison of Technological Characteristics With The Predicate Device:
The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. The following characteristics are similar between the subject device and predicate devices:

- Indications for use
- Principle of operation
- Technological characteristics
- Performance testing

Comparison with Predicate Devices

Item	Primary Predicate Device K070474 TMR	Reference Device K153696	Subject Device TrueRelief
Intended Use / Indications for Use	TrueRelief is intended for temporary symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.	The Chattanooga Revolution Wireless is a clinical electrotherapy device intended for use under the supervision of a Healthcare Professional. As a TENS device, indications are for the following conditions: - Symptomatic relief and management of chronic, intractable pain - Post-surgical and post-trauma acute pain	The TrueRelief Device is intended for use under the supervision of a Healthcare Professional. TrueRelief is intended for temporary symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.
Prescription/ Professional Use Only or OTC	Prescription	Prescription/ Professional Use Only	Prescription/ Professional Use Only
Where used	Physician office, physical therapy clinic, hospital nursing home, post acute care, chiropractic clinic	Physician office, physical therapy clinic, hospital nursing home, post acute care, chiropractic clinic	Physician office, physical therapy clinic, hospital nursing home, post acute care, chiropractic clinic
Target population	Adult population	Adult population	Adult population
Battery or mains powered	Mains	Mains and battery operated	Mains
Principle of Operation	External nerve stimulator that generates an electrical pulse that is delivered to the tissue through the primary and secondary probes	External nerve stimulator that generates an electrical pulse that is delivered to the tissue through the primary and secondary probes	External nerve stimulator that generates an electrical pulse that is delivered to the tissue through the primary and secondary probes
Sterility	Non-Sterile	Non-sterile	Non-sterile
Materials	Patient contact material: 316L stainless steel	Patient contact material: stainless steel	Patient contact material: 316L stainless steel
Connection of device to electrodes	The device uses two electrodes(probes) using a single channel. At one end of each probe is a 316 stainless	Stimulation Module is directly connected to the custom male SNAP assembled in the	The device uses two electrodes(probes) using a single channel. At one end of each probe is a

TrueRelief

Item	Primary Predicate Device K070474 TMR	Reference Device K153696	Subject Device TrueRelief
	steel tip that touches the patient and the other end of the stainless steel tip screws into the probe. On the other end of the probe is a cable which connects each probe to the device using a connector with pins.	electrode. User Interface (LCD and buttons) is physically separated (Remote Control) and communicates wirelessly with up to four (4) stimulation modules. Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.	316 stainless steel tip that touches the patient and the other end of the stainless steel tip screws into the probe. On the other end of the probe is a cable which connects each probe to the device using a connector with pins.
Power Supply	115 VAC, 60Hz input 12 volt DC output	Rechargeable battery	115 VAC, 60Hz input 12 volt DC output
Electrical Type	Type BF	NA Battery operated device	Type BF
Patient Leakage Current - Normal Condition (µA)	<100uA patient leakage	NA Battery operateddevice	<100uA patien tleakage
Patient Leakage Current - Single Fault Condition (µA)	<300uA line leakage	NA Battery operateddevice	<300uA line leakage
Number of Output Channels	1	0, 2, or 4	1
Method of Channel Isolation	Transformer isolated.	Each channel is the middle of a H Bridge. Except when it is activated, each channel is always in high impedance state	Transformer isolated.
Regulated Current or Regulated Voltage (output signals only)	Regulated current on only channel	Regulated current on all channels	Regulated current on only channel
Maximum Current (RMS) Density (mA/cm2)	14mA/cm2 Average of 2.1mA/cm2	1.34mA/cm2	14mA/cm2 Average of 2.1mA/cm2
Maximum Power Density [mW/cm^2]	79 mW/cm2 @500Ω Average of 11mW/cm2 @500Ω	14.4 [mW/cm^2] @500Ω	79 mW/cm2 @500Ω Average of 11mW/cm2 @500Ω
Output Voltage	Range of normal use: 50-60 V Peak pulse amplitude: 200 V	60 V @ 500 Ω 180V @ 2 kΩ 180 V @ 10 kΩ	Range of normal use: 50-60 V Peak pulse amplitude: 200 V
Pulse Rate	1 to 400 (+10%) Pulse / Second (Low) 4,000 (-5%) to 20,000 (+10%) Pulse/Second (High)	35 - 80 Hz	1 to 400 (+10%) Pulse / Second (Low) 4,000 (-5%) to 20,000 (+10%) Pulse/Second (High)

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Item	Primary Predicate Device K070474 TMR	Reference Device K153696	Subject Device TrueRelief
Pulse Duration	0.24-0.74 millisecond (Low) 15-25 microsecond (High)	300 to 400 [µs] (microseconds)	0.24-0.74 millisecond (Low) 15-25 microsecond (High)
Output Current (maximum)	8.9 milliamps (at body resistance > 10.11K ohms)	120 mA @ 500 Ω 90 mA @ 2 kΩ 18 mA @ 10 kΩ	8.9 milliamps (at body resistance > 10.11K ohms)
Maximum Charge Per Pulse	7 µC	36 [µC] @ 500Ω	7 µC
Wave Form Shape	Rectangular	Rectangular	Rectangular
Maximum Amplitude	No load – 200 V Peak With 50K ohm load – 175 V Peak	60 V @ 500 Ω 180V @ 2 kΩ 180 V @ 10 kΩ	No load – 200 V Peak With 50K ohm load – 175 V Peak

Summary of Performance Testing:

Electrical Safety: The TrueRelief Device was tested and certified to comply with recognized standards for electrical safety (IEC 60601-1, IEC 60601-2-10, IEC 60601-1-6).

Electromagnetic Compatibility: The TrueRelief Device was tested and certified to comply with recognized standards for electromagnetic compatibility (IEC 60601-1-2).

Usability/Human Factors: Usability/Human Factors were evaluated, which demonstrated that the established requirements for usability were met, and the device's design is appropriate for the intended users and use environment. The result of this evaluation substantiates the acceptability of the use-related risks identified during the risk assessment activities.

Conclusion:

Based on the performance testing and the similarities of the indications for use and the technological characteristics, it can be concluded that the TrueRelief Device is as safe and effective as, and substantially equivalent to, the predicate device(s).